

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Oct 2026

Comparison of the effect of morphine and oxycodone in relieving pain in patients with bone metastasis pain

Protocol summary

Study aim

The effect of morphine with oxycodone in relieving pain in patients is compared with pain due to bone metastases

Design

Randomized clinical trial, with parallel groups, double-blind, phase 3 on 32 patients, block method and online software www.sealedenvelope.com were used for randomization.

Settings and conduct

This study is a double-blind randomized clinical trial in Khansari Hospital in Arak in 1399 with easy sampling. All patients who are candidates for analgesia and have inclusion criteria will be evaluated as the study population after completing the informed consent form. In this study, 32 patients are divided into two completely equal groups using morphine and oxycodone using block randomization. Due to the two-sided blindness of the study, in this study, only specialists The person in charge of the study is aware of the type of study and the study groups, while patients are not aware of the type of prescription drug. It is not aware and only recognizes groups based on A and B and fills checklists accordingly.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with malignancy with bone metastasis confirmed by bone scan Candidate for analgesia, was less than 6. Exclusion criteria: history of diabetes and kidney failure, bone fracture, hypotension, bradypnea

Intervention groups

In the first intervention group, 16 patients received 5 mg morphine intravenously and placebo tablets only once at the beginning of the intervention and in the second intervention group, 16 patients took two 5 mg oxycodone tablets orally, together and by injection alone. Once received at the beginning of the intervention.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201202049575N1**

Registration date: **2020-12-09, 1399/09/19**

Registration timing: **prospective**

Last update: **2020-12-09, 1399/09/19**

Update count: **0**

Registration date

2020-12-09, 1399/09/19

Registrant information

Name

Mahdi Farahani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3505

Email address

m.mahdi.f.13732324@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of morphine and oxycodone in relieving pain in patients with bone metastasis pain		Used
Public title	The effect of morphine and oxycodone on bone metastatic pain	Assignment Parallel
Purpose	Supportive	Other design features
Inclusion/Exclusion criteria	Inclusion criteria: All patients with malignancy whose bone metastasis has been confirmed by bone scan and are candidates for analgesia. Pain intensity less than 6 based on vas ruler Exclusion criteria: Have low blood pressure, Bradypnea Have a bone fractures History of diabetes and kidney failure	Secondary Ids empty
Age	From 18 years old to 60 years old	Ethics committees <u>1</u>
Gender	Both	Ethics committee Name of ethics committee thics committee of Arak University of Medical Sciences
Phase	3	Street address Payambar-e-azam Complex, Basij Sq., Sardasht
Groups that have been masked	• Participant • Care provider • Outcome assessor	City Arak
Sample size	Target sample size: 32	Province Markazi
Randomization (investigator's opinion)	Randomized	Postal code 3848176341
Randomization description	Using block randomization method and online statistical software (www.sealedenvelope.com), 32 patients will be divided into two equal groups of intervention and control in 8 blocks of 4. To hide random sequences, the sealed envelope method is used. First, a random sequence is created by one of the mentioned methods. , Are prepared and each of the random sequences created is recorded on a card and the cards are placed in the envelopes in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, according to the order of entry of eligible participants into the study, one of the envelopes is opened in order and the assigned group of the participant is revealed.	Approval date 2020-11-08, 1399/08/18
Blinding (investigator's opinion)	Double blinded	Ethics committee reference number IR.ARAKMU.REC.1399.230
Blinding description	Due to the double-blindness of the study, blindness is such that only the relevant specialist in charge is aware of the type of the study and groups , while patients are not aware of the type of prescription drug and blind using injectable and oral placebo. Also, the clinical caregivers and interns in charge of the project, who are in charge of filling out the checklists, are not aware of the type of groups based on the prescription drug and only recognize the groups based on A and B and check the checklists.	Health conditions studied <u>1</u> Description of health condition studied Bone metastasis
Placebo		ICD-10 code C41
		ICD-10 code description Malignant neoplasm of bone and articular cartilage of other and unspecified sites
		Primary outcomes <u>1</u> Description Pain
		Timepoint Before the intervention, 30 minutes, 2 hours and 6 hours after the intervention
		Method of measurement visual analogue scale for pain
		Secondary outcomes empty
		Intervention groups

1

Description

First intervention group: In the first group, 16 patients received morphine sulfate (Darupakhsh-Iran) 5 mg intravenously once at the beginning of the intervention and two placebo tablets orally once at the beginning of the intervention.

Category

Treatment - Drugs

2

Description

Second intervention group: In the second group, 16 patients receive two 5 mg oxycodone tablets (Shafa-Iran) orally and simultaneously, and only once at the beginning of the intervention and an injectable placebo of 5 ml, once at the beginning of the intervention.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Mahdi Farahani

Street address

Valiasr sq.

City

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3814957558

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

Street address

Payambar-e-azam Complex, Basij Sq., Sardasht

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3848176341

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research@arakmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arak University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mahdi Farahani

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Person responsible for updating data**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Mahdi Farahani

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

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Province